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Picker 510(k) Notice

Clinix mp

Summary of Safety and Effectiveness

This is a summary of the information submitted by Picker International, Inc. to the Office of Device Evaluation (DRAERD) of the FDA as required by the Federal Food, Drug, and Cosmetic Act as amended on November 18, 1990 in section 513(f)(3) for the Universix 190.

The *Clinix mp* is a remote controlled R/F X-ray system intended for radiographic/ fluoroscopic examinations of the entire human anatomy. This device may include signal analysis and display equipment, patient equipment supports, components and accessories.

Functional specifications and operator's instructions (preliminary) are included in the attachments. Final documentation will be provided with production units.

The *Clinix mp* is substantially equivalent to legally marketed devices. The *Clinix mp* is under control of health care professionals who are trained and responsible for fluoroscopic examinations. The *Clinix mp* will be certified to comply with Federal Diagnostic X-ray Performance Standards. Labeling (Product Bulletin and Operator's Manual) will be provided to the user of the equipment.

MECALL adheres to FDA GMPs, 21 CFR 1020.30-31, voluntary standards for safety/effectiveness (UL 187) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and radiation).

Effectiveness is established by MECALL's evaluation throughout all phases of the *Clinix mp* development. The product will perform in accordance with the development specifications. The *Clinix mp* represents the current state-of- the-art technology, therefore, is equivalent to legally marketed remote C-arm systems.

MECALL has reviewed all known information and performed an investigation as to the causes of safety/effectiveness concerning the *Clinix mp*. In addition, all information contained in this 510(k) Notice is accurate and complete.